REMARKS

Preliminary matters

Applicants file a supplemental Form PTO/SB/08 listing the Konno et al. reference and a publication date of 2003 in response to the Examiner's previous position that the reference was not considered because no date was given. The Examiner is respectfully requested to consider the reference.

Amendment summary

Subject matter from Claims 2-4 and 37 is incorporated into Claim 1. Claims 2-4 and 37 are canceled. Support for the location of the active in the micelle core may be found, e.g., on page 3, lines 7-10 of the present specification.

No new matter is added by this amendment, and Applicant respectfully submits that entry of this amendment is proper.

Status of the claims

Claims 1, 4-14, 20-25, 38, and 42-44 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Lobb et al. (J. Am. Chem. Soc., 2001, 123, 7913-7914) (hereinafter "Lobb"). Claims 2, 3, 28, and 37 have been rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Lobb in view of Konno et al. (Biomaterials, 2001, 22, 1883-1889) (hereinafter "Konno"). In addition, Claims 15 and 26-27 have been rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Lobb. Finally, Claims 20 and 42 have been rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Lobb in view of Coessens et al. (Prog. Polym. Sci., 2001, 26, 337-377) (hereinafter "Coessens").

Response to rejections based on Lobb

In Paragraph No. 7 of the Office Action, Claims 1, 4-14, 20-25, 38, and 42-44 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Lobb. In Paragraph Nos. 18 and 28, Claims 15 and 26-27 have been rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Lobb.

As mentioned above, subject matter from Claims 2-3 and 37 has been incorporated into Claim 1. Applicant respectfully submits that the above rejections based on Lobb are therefore moot, and Applicant respectfully requests the reconsideration and withdrawal of these § 102 and § 103 rejections.

Response to rejection of Claims 2, 3, 28, and 37 under 35 U.S.C. § 103 based on Lobb in view of Konno

Claims 2, 3, 28, and 37 have been rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Lobb in view of Konno. Applicant respectfully submits that the presently claimed invention is not rendered obvious by the combined teachings of Lobb in view of Konno because it would not be obvious to incorporate the hydrophobic fluorescence probes of Konno into the micelles of Lobb at al, since the resultant nanoparticles would have no surface fluorescence probe, and would therefore not be expected to be effective for the use disclosed within Konno.

Present Claim 1 recites an aqueous composition comprising an amphiphilic block copolymer having a hydrophilic block and a hydrophobic block, dispersed in the form of micelles in the composition, and a biologically active compound having a measured and/or calculated partition coefficient between octanol and water of at least 1.5 associated with the

copolymer in the core of the micelles. In addition, the hydrophilic block has pendant zwitterionic groups.

With respect to Lobb, Applicant respectfully submits that the Office Action overlooked that the present claims recite that the aqueous composition comprises a biologically active compound associated with the polymer. There is no disclosure in Lobb of a biologically active compound associated with the polymer in an aqueous composition. At page 7914, right hand column, first full paragraph of Lobb, the final sentence reads "this indicates that MPC-DEA diblock copolymer micelles are also most likely biocompatible and therefore show considerable promise for drug delivery applications." However, there is no explanation in Lobb regarding how the micelles would be used for drug delivery. It is relevant that this sentence includes two speculative comments, the first being that the micelles are biocompatible, and the second being that the products may show considerable promise for drug delivery applications. Applicant notes that neither of these predictions is either further justified or proven with further data.

Applicant submits that the reference to using the copolymer micelles in a drug delivery application would, in the context of Lobb's disclosure, be understood to lead a person skilled in the art toward forming coatings on surfaces from the micellar compositions, which may then be used as drug delivery layers. For example, in the introductory paragraph (page 7913 of Lobb, left hand column, first paragraph), it is explained that phosphorylcholine (PC) based polymers can be used to produce surfaces which are remarkably resistant to protein absorption and cell adhesion. This paragraph goes onto explain that it would be desirable for such polymers to be synthesized in a controlled manner, so as to form polymers having controlled molecular weight and low distribution of molecular weight. In the test method for biocompatibility, the polymer produced by the controlled polymerization conditions is coated onto a PET substrate to form a

coating. It is well known to deliver drugs from coatings of polymers on medical devices, such as stents. Accordingly, Applicant respectfully submits that the suggestion in Lobb to use the polymer micelles in a drug delivery application would be understood to be a suggestion to form coatings from the micellar compositions, which would then be used as drug delivery substrates.

With respect to Lobb in view of Konno, Applicant notes that the present claims recite the localization of the active in the core of the micelle. Applicant respectfully submits that the definition of the copolymer as being in the form of a micelle and the hydrophobic active being in the core of the micelle to provides additional distinctions over Lobb in view of Konno. In particular, in Konno, at page 1884, left hand column, first full paragraph, it is clear that the fluorescence probes which are to be loaded onto the nanoparticles must be at the surface. The surface arrangement of the hydrophobic portions is also clear from the schematic representation in Figure **2** in Konno. By contrast, the micelles of Lobb have hydrophilic entities at their surface, that is the MPC-derived components as illustrated in Figure **2** of Lobb on page 7194. Accordingly, the nanoparticles of Konno are very different from the micelles of Lobb.

In view of the above, Applicant respectfully submits that it would not be obvious to incorporate the hydrophobic fluorescence probes of Konno into the micelles of Lobb because the resultant nanoparticles would have no surface fluorescence probe, and would therefore not be expected to be effective for the use disclosed in Konno. Applicant therefore respectfully requests the reconsideration and withdrawal of this § 103 rejection.

Response to rejection of Claims 20 and 42 under 35 U.S.C. § based on Lobb in view of Coessens

Claims 20 and 42 have been rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Lobb in view of Coessens.

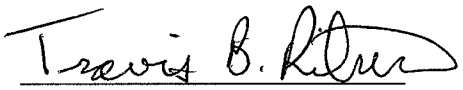
As mentioned above, subject matter from Claims 2-3 and 37 has been incorporated into Claim 1. Applicant respectfully submits that the above rejections based on Lobb are therefore moot, and also respectfully submits that Coessens was not cited for teachings that address the subject matter of Claims 2-3 and 37. Applicant therefore submits that the present rejection based on Lobb in view of Coessens has also been rendered moot, and respectfully requests the reconsideration and withdrawal of this § 103 rejection.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/506,805
Confirmation Number	5416
Filing Date	January 19, 2005
First Named Inventor	Andrew Lennard LEWIS
Art Unit	4173
Examiner Name	Kyle A PURDY
Attorney Docket Number	Q83534

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number	Document Number: Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3]	Foreign Patent Document: Number[4]	Foreign Patent Document: Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation[6]

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation[6]
		KONNO, et al., Enhanced solubility of paclitaxel using water-soluble and biocompatible 2-methacryloyloxyethyl phosphorylcholine polymers, 2003, pp. 210-215.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or follow the hyperlink from the title of the document to the intranet. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to indicate here if English language Translation is attached.